(54)

Inventor(s)
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(12) PATENT APPLICATION (19) AUSTRALIAN PATENT OFFICE				(11) Application No. AU 199745341 A1				
(54)	Title Syringe identification system							
(51)	International Patent Classif B65D 079/00 A61M 005/142 A61M 005/145 A61M 005/175	A61N	s) // 005/20 // 005/50 // 083/76					
(21)	Application No: 1997453	41		(22)	Date of	Filing:	1997.11.21	
(30)	Priority Data						•	
(31)	Number PO3791	(32)	Date 1996.11.22	2	(33)	Countr AU	ry	
(43)	Publication Journal Date:	1998	.05.28					
(71)	Applicant(s) Presnash Pty. Limited							

NON-CONVENTION - COMPANY (Employment Contract and associated with Prov)

P/00/008a Section 29 (1) Regulation 3.1(2)

AUSTRALIA

PATENTS ACT 1990

NOTICE OF ENTITLEMENT

We, Presnash Pty. Limited ACN 003 426 944, of 27 Park Road, Rydalmere, NSW 2116, Australia, being the applicant and nominated person in respect of Application No. 45341/97, state the following:-

1. The person nominated for the grant of the patent has entitlement from the actual inventors as follows:

If a patent were granted to the actual inventor in respect of the invention the nominated person would be entitled to have the patent assigned to it.

The person nominated for the grant of the patent is the applicant of the provisional application listed on the patent request form.

For and on behalf of
Presnash Pty. Limited

(Signature)

15-1-98

(Date)

Name: Kodney Brian Sava

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File: 20337

SHELSTON WATERS
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PATENTS ACT 1990

PATENT REQUEST FOR STANDARD PATENT

We, PRESNASH PTY. LIMITED 003 426 944, being the person identified below as the Applicant, request the grant of a patent to the person identified below as the Nominated Person, for an invention described in the accompanying standard complete specification.

Full application details follow:

Applicant:

PRESNASH PTY. LIMITED

Address:

27 Park Road, Rydalmere, NSW 2116, Australia.

Nominated Person:

- As above -

Address:

- As above -

Invention Title:

"SYRINGE IDENTIFICATION SYSTEM"

Name of actual Inventor/s:

Rodney Brian SAVAGE

ASSOCIATED PROVISIONAL APPLICATION DETAILS:

Application Number: PO3791 dated 22 November 1996

Drawing number recommended to accompany the abstract:

Address for service is:

SHELSTON WATERS **60 MARGARET STREET** SYDNEY NSW 2000

Attorney Code: SW

DATED this 21st Day of November, 1997.

PRESNASH PTY. LIMITED

Fellow Institute of Patent Attorneys of Australia a of SHELSTON WAILLS

To: The Commissioner of Patents WODEN ACT 2606

File:20337.00 Fee: \$280

AU9745341

(12) PATENT ABSTRACT (11) Document No. AU-A-45341/97 (19) AUSTRALIAN PATENT OFFICE

(54) Title
SYRINGE IDENTIFICATION SYSTEM

International Patent Classification(s)
(51)⁶ B65D 079/00 A61M 005/142 A61M 005/145

A61M 005/50 A61M 005/175 B65D 083/76

21) --- Application-No.-: 45341/97 ---

(22) Application Date: 21/11/97

(30) Priority Data

(31) Number PO3791

Date 22/11/96

(33) Country AU AUSTRALIA

(43) Publication Date: 28/05/98

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(57)

The control signal is generated by identification means associated with both the pump and the syringe. In the particular embodiment shown in Figures 1 to 3b, 8 and 9, the identification means takes the form of a coded magnetic strip 22 affixed to the syringe barrel 12, and a magnetic read/write head 24 mounted adjacent the cradle 10. As the syringe 2 is rotated in the cradle 10 from the first position to the second position, the magnetic head 24 reads information from the magnetic strip 22. Alternatively, the magnetic strip may be provided on the ears 16 of the syringe (see 22a) to be read by a different read/write head 24a. Subsequent comments about identification elements 22 and 24 are equally applicable to identification elements 22a and 24a respectively.

1. A system for the controlled delivery of a fluid, said system comprising a syringe pump and a disposable syringe, said pump including a holder adapted to releasably retain the syringe, identification means adapted to generate a control signal indicative of whether the syringe is of a suitable type, drive means adapted to progressively depress a plunger on the syringe to express the fluid therefrom, control means adapted to regulate

the drive means and to prevent the delivery of the fluid when said control signal indicates that the syringe is not of the suitable type, the holder being adapted to receive the syringe such that upon rotation of the syringe from a first position to a second position the syringe is retained by the holder and wherein the rotation of the syringe is used to facilitate the identification of the syringe by the identification means.

10. A syringe pump for controlled delivery of a fluid from a disposable syringe, said pump including a holder adapted to releasably retain the syringe, identification means adapted to generate a control signal indicative of whether the syringe is of a suitable type, drive means adapted to progressively depress a plunger on the syringe to express the fluid therefrom, control means adapted to regulate the drive means and to prevent the delivery of the fluid when said control signal indicates that the syringe is not of the suitable type, the holder being adapted to receive the syringe such that upon rotation of the syringe from a first position to a second position the syringe is retained by the holder, and wherein the rotation of the syringe is used to facilitate the identification of the syringe by the identification means.

AUSTRALIA

PATENTS ACT 1990

COMPLETE SPECIFICATION

FOR A STANDARD PATENT

ORIGINAL

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SYDNEY NSW 2000

Invention Title:

SYRINGE IDENTIFICATION SYSTEM

Details of Associated Provisional Application No. PO3791 dated 22 November, 1996

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

TECHNICAL FIELD

The present invention relates to a system comprising a syringe pump and disposable syringe for the controlled delivery of a fluid. The invention also relates to a novel syringe-pump and disposable syringe for the controlled delivery of a fluid.

BACKGROUND OF THE INVENTION

It is common practice in hospitals, clinics, medical centres and similar institutions to use a large range of disposable sterile syringes for administration of drugs, anaesthetics, contrast media and a variety of other fluids, to patients requiring such treatment or diagnosis. Generally, disposable sterile syringes are used to minimise the possibility of contamination or transfer of infectious agents between patients.

A variety of automated systems are available for delivering fluids to patients at preset rates or dosages, according to data provided by an operator. The mechanisation of these systems provides an additional safety measure for both the patient and the practitioner, by reducing the likelihood of excessive or inappropriate dosages being administered through human error, and in some cases can enable the administration of dosages at high pressures and flow rates unattainable with manual methods.

Automatic fluid delivery from plastic disposable syringes is particularly useful in fields such as radiology, where contrast media and the like must be delivered at relatively high rates and pressures. Due to the relatively small market for specialty syringes of this type, they tend to be relatively costly. This in turn has made it tempting for practitioners and hospitals operating under tight budgetary constraints to reuse such syringes, with potentially fatal consequences. Also, there have been instances where standard manual syringes have been substituted for specialised syringes, which carries

with it the risk of syringe failure, administration of the fluid in incorrect volumes or at incorrect pressures or flow rates, or at least patient discomfort or injury.

It is an object of the present invention to overcome or at least ameliorate one of more of the disadvantages of the prior art.

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SUMMARY OF THE INVENTION

Accordingly, the present invention provides a system for the controlled delivery of a fluid, said system comprising a syringe pump and a disposable syringe, said pump including a holder adapted to releasably retain the syringe, identification means adapted to generate a control signal indicative of whether the syringe is of a suitable type, drive means adapted to progressively depress a plunger on the syringe to express the fluid therefrom, control means adapted to regulate the drive means and to prevent the delivery of the fluid when said control signal indicates that the syringe is not of the suitable type, the holder being adapted to receive the syringe such that upon rotation of the syringe from a first position to a second position the syringe is retained by the holder and wherein the rotation of the syringe is used to facilitate the identification of the syringe by the identification means.

The present invention also provides a syringe pump for controlled delivery of a fluid from a disposable syringe, said pump including a holder adapted to releasably retain the syringe, identification means adapted to generate a control signal indicative of whether the syringe is of a suitable type, drive means adapted to progressively depress a plunger on the syringe to express the fluid therefrom, control means adapted to regulate the drive means and to prevent the delivery of the fluid when said control signal indicates that the syringe is not of the suitable type, the holder being adapted to receive

the syringe such that upon rotation of the syringe from a first position to a second position the syringe is retained by the holder, and wherein the rotation of the syringe is used to facilitate the identification of the syringe by the identification means.

The present invention further provides a disposable syringe for use with the system, said syringe including identity data to identify the syringe and/or contents thereof, said syringe being adapted to be inserted in the holder of the syringe pump in a first position and to be rotated in the holder to a second, dispensing position; said identity data being located on the syringe such that the rotation of the syringe is used to facilitate the identification of the syringe by the identification means.

The identity data of the syringe is used to indicate whether the syringe to be used is of a suitable type. The data may be used to indicate the particular type of syringe, the nature of the contents of the syringe, and/or whether the syringe has previously been used.

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In one embodiment of the invention the control signal generated by the identification means indicates whether the syringe has previously been used and the control means is adapted to regulate the drive means and to prevent the delivery of the fluid when the control signal indicates that the syringe has previously been used.

Preferably, the syringe pump further includes means to alter or delete the identity data of the syringe, thereby preventing subsequent reuse of the syringe.

In an alternative embodiment, the identification means includes code reading means to read a code associated with the syringe. More preferably, the identification means further includes a comparison means to compare the code with stored reference values, the control signal then being generated as a result of the comparison.

In one particular embodiment, the code is stored on a magnetic strip on the syringe, and the code reader is a magnetic strip reading head.—It is desirable that the pump also includes means to alter or delete the code so as to indicate that the syringe has previously been used. In the preferred form, the altering means is incorporated into the magnetic strip reading head, which is adapted to over-write, wipe or obliterate the code on the syringe.

In another embodiment, the code is stored as an optical code associated with the syringe, and the code reader is an optical code reader. In this embodiment, the reference values may include data identifying codes associated with a preselected number of previous syringes, the control signal being indicative of whether the syringe in the holder has previously been used with that pump, or a linked network of pumps. In one embodiment, the optical code may take the form of a barcode.

In yet another embodiment, the identification means can take the form of a mechanical system. For example, a resilient ball or plug may be retained within a longitudinal bore extending into the plunger. Switches mounted on a pushrod associated with the pump for depressing the plunger are then used to ascertain whether the ball or plug is in the correct position.

Other mechanical embodiments may include the use of a frangible membrane disposed within a longitudinal bore in the plunger. Alternatively, protrusions, tabs or dimples located on the syringe may be employed to provide the necessary identity data.

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Preferably, the syringe is locked into place in the holder by rotation through about 90°, the pump being disabled until the syringe is locked into position. Preferably

also, the twisting action is used to facilitate reading of the magnetic strip, optical code, or any mechanical keying used to identify whether the syringe has previously been used.

BRIEF DESCRIPTION OF FIGURES

A preferred embodiment of the present invention will now be described, by way of example only, with reference to the following drawings in which:

Figure 1 is a simplified perspective view of a syringe pump and disposable syringe forming the system according to the invention;

Figure 2a is an end view of the syringe and syringe holder, with the syringe shown in a first position for the insertion and removal of the syringe from the holder;

Figure 2b is the same end view as shown in Figure 2a, but with the syringe shown in a second, dispensing position;

Figure 3a is a sectional view of an alternative embodiment of the syringe and syringe holder illustrating an identification means comprising a magnetic strip on the ears of the syringe and a magnetic reader on the syringe holder, with the syringe shown in a first position for insertion and removal of the syringe from the holder;

Figure 3b is the same sectional view as shown in Figure 3a, but with the syringe shown in a second, dispensing position;

Figure 4 is a perspective view showing another embodiment of the invention which employs a mechanical identification means;

Figure 5 is a longitudinal section through the syringe handle and pusher assembly of the embodiment shown in Figure 4;

Figure 6 is a rear view of the syringe handle shown in Figures 4 and 5;

Figure 7 is a longitudinal section through the syringe handle showing an alterative embodiment of the pump shown in Figures 4 to 6;

Figure 8 is a perspective view of an alternative embodiment, adapted for use with syringes without handles; and

Figure 9 is a longitudinal section of the pump and syringe of Figure 8.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawings, a syringe pump designated generally as 1 provides for the controlled delivery of a fluid from a disposable syringe 2. The pump 1 includes a holder 4 adapted releasably to hold the syringe 2, and drive means 6 adapted selectively to depress the syringe plunger 8.

Holder 4 includes a generally channel-shaped cradle 10 to a support a barrel 12 of the syringe 2 in a generally horizontal orientation. It will be appreciated, however, that the holder may be configured to position the syringe 2 in any convenient orientation, depending upon the circumstances. Holder 4 also includes a retaining groove 14 to axially locate ears 16 of the syringe during depression of the plunger 8 by the drive mechanism 6.

The cradle 10 and groove 14 are configured such that the syringe 2 may initially be inserted into the holder 4 in a first position with its ears 16 engaging the groove 14 and extending essentially vertically, as best shown in Fig. 2a. The body of the syringe 2 is then rotated about its principal (longitudinal) axis through approximately 90 degrees to a second, dispensing position as shown in Figure 2b. Preferably the groove 14 includes a stop 18 which acts to define the second position. In the preferred embodiment the drive mechanism 6 is adapted such that it will not operate to depress the plunger 8 unless and

until the syringe 2 has reached the second position ready for dispensing, as best shown in Figure 3b.

The drive means 6 includes a pushrod 20 which is selectively advanced and withdrawn with respect to the cradle 10 by an electric motor and worm gear assembly (not shown). A rotary encoder or the like provides information on the position and rate of advance of the pushrod 20. This aspect of the syringe pump 1 is well known to those skilled in the art and so will not be described in detail.

The syringe pump also includes control means in the form of a microcomputer (not shown) which enables the rate at which the plunger 8 is depressed to be varied.

Typically, the control means is accessible through a keypad (not shown) associated with the pump 1, which allows a user to accurately program the delivery of the fluid by the system.

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As well as being programmable by keypad input, the control means is responsive to a control signal indicative of whether the syringe 2 in the holder 4 is suitable for the injection (as for example, whether the syringe is of the correct type or has previously been used). The control signal is generated by identification means associated with both the pump and the syringe. In the particular embodiment shown in Figures 1 to 3b, 8 and 9, the identification means takes the form of a coded magnetic strip 22 affixed to the syringe barrel 12, and a magnetic read/write head 24 mounted adjacent the cradle 10. As the syringe 2 is rotated in the cradle 10 from the first position to the second position, the magnetic head 24 reads information from the magnetic strip 22. Alternatively, the magnetic strip may be provided on the ears 16 of the syringe (see 22a) to be read by a

different read/write head 24a. Subsequent comments about identification elements 22 and 24 are equally applicable to identification elements 22a and 24a respectively.

In one preferred form of the invention, the data contained on the magnetic strip 22 provides information about the type of syringe and/or whether the syringe 2 has been previously used. This may be achieved by providing the magnetic strip 22 with a simple code which is recognisable by the microcomputer. If the code is incorrect or is not readable, the controller means 6 will not allow the drive means to be operated to depress the plunger 8, thereby preventing the syringe 2 being reused.

When the syringe 2 is rotated to remove it from the cradle 10, the magnetic head 24 erases or writes over the information on the magnetic strip 22. Alternatively, a small electro-magnet (not shown) may be used to erase the magnetic strip as the syringe is removed. In either case, any attempt to reuse the syringe in a syringe pump incorporating the present invention will fail, because the magnetic strip 22 will no longer bear an appropriate code.

Other information may be provided on the magnetic strip 22. For example, it may contain details of the type of drug or chemical in the syringe, the date of manufacture or expiry, batch codes, data relating to the type and size of syringe, default delivery rate parameters for the drug or chemical involved, prohibited delivery rates, or even individual dosage information for a particular patient. Furthermore, any one of these pieces of information may be used to identify whether the syringe has previously been used.

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This particular embodiment provides a number of substantial advantages. Firstly, the information on the magnetic strip 22 is not readable or alterable by the user, other

than through an interface associated with the pump (not shown). Furthermore, the code can be kept simple and may simply form part of other information. Users can not short-circuit the system by peeling off the magnetic strip 22 to use on another syringe, because it is the strip itself which is altered, rather than the syringe. Other advantages include the robustness of magnetic equipment, its lack of need for power whilst on standby and its relatively low cost.

In another embodiment (not shown), the identification means takes the form of an optical symbol or code located on the syringe, and an optical reader associated with the syringe pump. In a basic form the symbol could comprise a simple marking such as a dot or the like which is used to indicate the syringe. In another, preferred form, the optical code may comprise a barcode label printed directly on or affixed to the syringe at a suitable location. As with the magnetic strip embodiment, the syringe is placed in the cradle and then rotated to a dispensing position. The barcode reader then scans the barcode label. Unlike the magnetic strip system, the preferred use of barcode labels requires that the syringe pump incorporate a memory facility to store information related to previously scanned barcodes. This in turn requires that each barcode is unique, or at least drawn from a relatively large set of possible barcodes. By scanning the barcode of the syringe presently in the holder and comparing it with the previously stored barcodes, a control signal indicative of whether the syringe has been used is generated, and the controller prevents depression of the plunger if such use has occurred.

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The label may be positioned at any convenient point on the syringe, whether on the barrel or the plunger. Whilst a unique identifier would be preferable, it is believed that reuse of syringes would be actively discouraged by using a finite set of barcodes which

are randomly applied to syringes, perhaps in a batchwise fashion. The memory facility may store anything from a handful to many hundreds of barcodes from previous syringes, although clearly the security of the system is increased for larger numbers of codes stored and codes available. Modern memory capacities enable hundreds or even thousands of codes and other information to be stored if desired.

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In a preferred form of the barcode embodiment, the memory is non-volatile to prevent it being cleared by accidental or intentional removal of power to the pump. As with the magnetic embodiment, it is possible to include with the identification code other information relating to syringe size or type, the drug or chemical involved and dosages.

Referring to Figures 4 to 7, yet another embodiment of the invention uses a mechanical system to generate a control signal indicative of whether the syringe 2 to be used is of a suitable type. One presently envisaged form of mechanical coding is shown in Figures 4 to 6. In this embodiment, the plunger 8 includes a blind longitudinal bore 30. A resilient ball 32 is retained at a preselected position within the bore 30 by sufficient friction to prevent movement during transportation and handling. The requisite friction may be achieved by providing the bore 30 with a number of internal longitudinally extending ridges 34 which engage the resilient ball 32.

As best shown in Figure 5, first and second rods 36, 38 connected to depressible switches 40, 42 extend from the end of the pushrod 20 towards the plunger 8. The first rod 36 is the longer of the two and is positioned such that, after locking the syringe 2 into the holder 4, as described above, it enters the bore 30 as the pushrod 20 is advanced. When the distal end of the first rod 36 encounters the resilient ball 32, the first switch 40 is depressed. As the pushrod 20 continues to advance, the ball 32 is pushed deeper into

advances from the first rod's engagement with the ball 32 before the distal end of the second rod 38 engages the surface of the plunger handle 44 adjacent the entrance to the bore 30, thereby closing the second switch 42. If the distance (shown as 'D' in the figures) is outside acceptable parameters, the pump 1 will not operate and the pushrod 20 will withdraw to enable the syringe 2 to be removed. If there is an attempt to reuse a syringe 2, the second rod 38 will engage the handle 44 simultaneously or too soon after the first rod 36 engages the ball, and the plunger 8 will not be depressed. The critical position of the ball 32 and the depth and blind nature of the longitudinal bore 30 makes tampering with a used syringe 2 of this type relatively difficult.

Another mechanical embodiment is shown in Figure 7, where the resilient ball 32 is replaced by a membrane 46 formed from frangible material such as paper, plastics or the like extending across the bore 30 at a predetermined position. The pushrod 20 used with this embodiment is similar to that in Figure 5, although the end of the first rod 36 is made slightly sharper. As best shown in Figure 7, the first rod 36 initially enters the bore 30 as the pushrod 20 is advanced, and engages the membrane 46. The first switch 40 is depressed by the first rod 36 due to the resilient nature of the membrane 46. However, further advancement of the pushrod 20 causes the end of the first rod 36 to pierce the membrane 46, the control means once again measuring the distance 'D' advanced by the pushrod 20 before the second rod 38 engages the plunger handle 44. As before, if 'D' is outside expected parameters, the controller will prevent depression of the plunger. Any attempt to reuse a syringe will result in the first switch not being depressed, which will prevent the pump from operating. Another variation of this

embodiment makes use of a simple control tab, which is broken off or deformed when the syringe is first used and the absence of which prevents subsequent use.

The identification means may comprise one or more dimples or tabs located on the barrel or ears of the syringe (in place of identifying elements 22 or 22a) and coded to identify the particular syringe. The dimples or tabs could be read by a sensitive switch or piezo device upon loading of the syringe as previously described. Upon use of the syringe, the dimples or tabs could be flattened or erased during the process of twisting and removing the syringe, thereby rendering the syringe unusable for a subsequent injection.

The present invention provides a relatively simple and effective system for ensuring that a syringe of a suitable type is used for each injection of liquid when using a powered syringe pump. This in turn substantially decreases the possibility of patient to patient infection. The invention thus provides a number of practical and commercial advantages over the prior art.

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Although the invention has been described with reference to specific examples, it will be appreciated by those skilled in the art that the invention may be embodied in many other forms.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

- 1. A system for the controlled delivery of a fluid, said system comprising a syringe pump and a disposable syringe, said pump including a holder adapted to releasably retain the syringe, identification means adapted to generate a control signal indicative of

 5 whether the syringe is of a suitable type, drive means adapted to progressively depress a plunger on the syringe to express the fluid therefrom, control means adapted to regulate the drive means and to prevent the delivery of the fluid when said control signal indicates that the syringe is not of the suitable type, the holder being adapted to receive the syringe such that upon rotation of the syringe from a first position to a second position the syringe is retained by the holder and wherein the rotation of the syringe is used to facilitate the identification of the syringe by the identification means.
 - 2. A system for the controlled delivery of a fluid as claimed in claim 1, wherein said identification means includes code reading means to read a code associated with the syringe.
- 3. A system for the controlled delivery of a fluid as claimed in claim 2, wherein the identification means further includes means to compare the code with stored reference values, the control signal being generated as a result of the comparison.
 - 4. A system for the controlled delivery of a fluid as claimed in claim 3, wherein the code is stored on a magnetic strip on the syringe and the code reader is a magnetic strip reading head.

- 5. A system for the controlled delivery of a fluid as claimed in claim 1, wherein the control signal generated by the identification means indicates whether the syringe has previously been used, said control means being adapted to regulate the drive means and to prevent the delivery of the fluid when the control signal indicates that the syringe has previously been used.
- 6. A system for the controlled delivery of a fluid as claimed in claim 2, further including altering means to change the code to indicate that the syringe has been used.
- A system for the controlled delivery of a fluid as claimed in claim 2,
 wherein said code comprises an optical code and said code reader comprises an optical code reader.
 - 8. A system for the controlled delivery of a fluid as claimed in claim 4, further including altering means to alter the code so as to indicate that the syringe has previously been used.
 - 9. A system for the controlled delivery of a fluid as claimed in claim 8, wherein the altering means is incorporated into the magnetic strip reading head and is adapted to over-write, wipe or obliterate the code on the syringe.
- 10. A syringe pump for controlled delivery of a fluid from a disposable syringe, said pump including a holder adapted to releasably retain the syringe, identification means adapted to generate a control signal indicative of whether the syringe is of a suitable type, drive means adapted to progressively depress a plunger on the syringe to express the fluid therefrom, control means adapted to regulate the drive means and to prevent the

delivery of the fluid when said control signal indicates that the syringe is not of the suitable type, the holder being adapted to receive the syringe such that upon rotation of the syringe from a first position to a second position the syringe is retained by the holder, and wherein the rotation of the syringe is used to facilitate the identification of the syringe by the identification means.

11. A disposable syringe for use with the system as claimed in claim 1, said syringe including identity data to identify the syringe and/or contents thereof, said syringe being adapted to be inserted in the holder of the syringe pump in a first position and to be rotated in the holder to a second, dispensing position; said identity data being located on the syringe such that the rotation of the syringe is used to facilitate the identification of the syringe by the identification means.

DATED this 21st Day of November, 1997

PRESNASH PTY. LIMITED

Attorney: STUART M. SMITH
Fellow Institute of Patent Attorneys of Australia
of SHELSTON WATERS

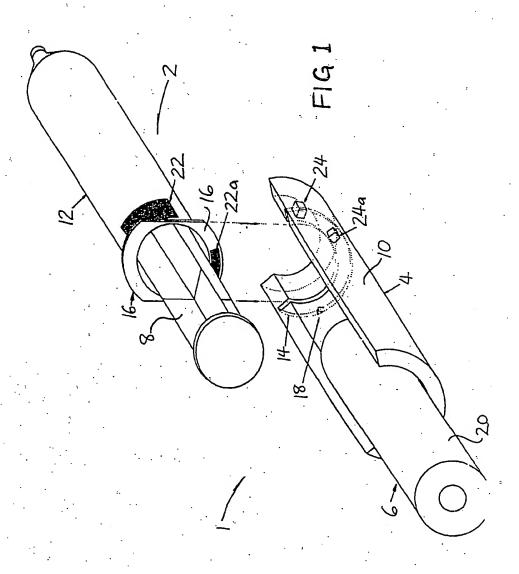
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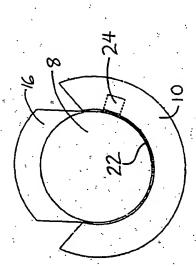
ABSTRACT

The present invention relates to a system comprising a syringe pump and disposable syringe for the controlled delivery of a fluid.

In one form the invention provides a system for the controlled delivery of a fluid, the system comprising a syringe pump and a disposable syringe; the pump including a holder adapted to releasably retain the syringe, identification means adapted to generate a control signal indicative of whether the syringe is of a suitable type, drive means adapted to progressively depress a plunger on the syringe to express the fluid therefrom, control means adapted to regulate the drive means and to prevent the delivery of the fluid when said control signal indicates that the syringe is not of the suitable type, the holder being adapted to receive the syringe such that upon rotation of the syringe from a first position to a second position the syringe is retained by the holder and wherein the rotation of the syringe is used to facilitate the identification of the syringe by the identification means.

The invention also provides a novel syringe pump and disposable syringe for use in the system.





F1G 2a

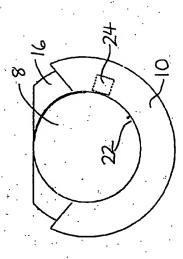
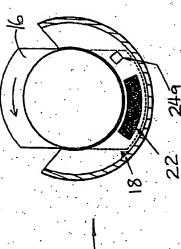
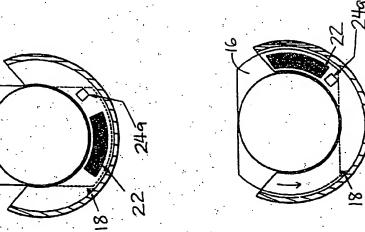
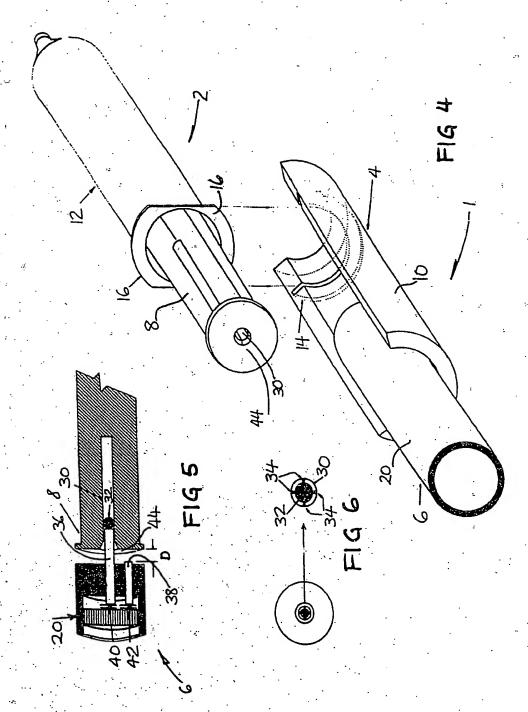
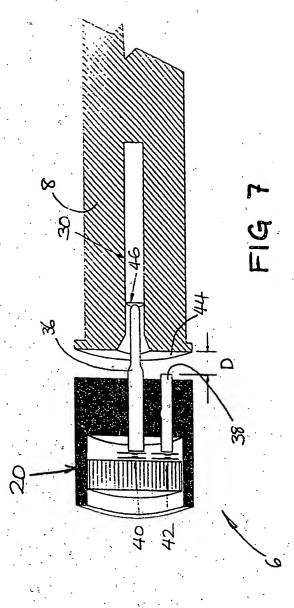


FIG 26









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